

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE  
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.  
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (GBW)

REDACTED - PUBLIC VERSION

**SAREPTA THERAPEUTICS, INC. AND THE UNIVERSITY OF WESTERN  
AUSTRALIA'S OPENING BRIEF IN SUPPORT OF  
THEIR MOTIONS FOR SUMMARY JUDGMENT**

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TABLE OF ABBREVIATIONS

<b>Abbreviation</b>	<b>Description</b>
'851 Patent	U.S. Patent No. 9,994,851
'590 Patent	U.S. Patent No. 10,227,590
'827 Patent	U.S. Patent No. 10,266,827
'361 Patent	U.S. Patent No. 9,708,361
'092 Patent	U.S. Patent No. 10,385,092
'461 Patent	U.S. Patent No. 10,407,461
'106 Patent	U.S. Patent No. 10,487,106
'741 Patent	U.S. Patent No. 10,647,741
'217 Patent	U.S. Patent No. 10,662,217
'322 Patent	U.S. Patent No. 10,683,322
ASO	Antisense oligonucleotide
<b><i>Bold and Italic</i></b>	Emphasis added unless indicated otherwise
Ex. ____	Exhibit ____ <sup>1</sup>
NS	Plaintiff/Counter-Defendants Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.
NS Japan	Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd.
NS Pharma	Counter-Defendant NS Pharma, Inc.
NS Patents	U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; 10,683,322
PTO	United States Patent and Trademark Office
Sarepta	Defendant/Counter-Plaintiff Sarepta Therapeutics, Inc.
SOF	Concise Statement of Facts in Support of Sarepta Therapeutics, Inc. and the University of Western Australia's Motions for Summary Judgment
UWA	Counter-Plaintiff The University of Western Australia
Wilton Patents	U.S. Patent Nos. 9,994,851; 10,227,590; and 10,266,827
Wilton Product Patents	U.S. Patent Nos. 9,994,851; 10,227,590

<sup>1</sup> Refers to Exhibits to the accompanying Declaration of Megan E. Dellinger in Support of Sarepta Therapeutics, Inc. and The University of Western Australia's Motions for Summary Judgment and Motions to Exclude Certain Opinions and Testimony of Plaintiff/Counter-Defendants' Experts.



## **I. INTRODUCTION**

Sarepta and UWA respectfully request that the Court grant summary judgment that:

(1) NS infringes claims 1 and 2 of U.S. Patent No. 9,994,851 and claims 1 and 2 of U.S. Patent No. 10,227,590;

(2) Nippon Shinyaku Co., Ltd. (“NS Japan”) is not entitled to recover lost profits damages from Sarepta for any alleged infringement of the NS Patents; and

(3) the Wilton Patents are not unenforceable for inequitable conduct and there is no *Walker Process* fraud.

Pursuant to the Court’s Scheduling Order (D.I. 143, ¶13(d)), Sarepta and UWA rank the motions in the above order.

## **II. LEGAL STANDARD FOR SUMMARY JUDGMENT**

A court should grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the Court must consider “the substantive evidentiary standard of proof that would apply at the trial on the merits” and ask “whether a fair-minded [factfinder] could return a verdict for the plaintiff on the evidence presented.” *Anderson v. Liberty Lobby*, 477 U.S. 242, 252 (1986). Summary judgment must be granted against a party that has failed to introduce evidence sufficient to establish the existence of an essential element of that party’s case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

## **III. NATURE AND STAGE OF THE PROCEEDINGS**

NS initiated this litigation on July 13, 2021, asserting that Sarepta infringes the claims of U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; and 10,683,322. Sarepta and UWA counter-sued for infringement of U.S. Patent Nos. 9,994,851;

[REDACTED]

10,227,590; and 10,266,827. Fact and expert discovery are closed. Trial is scheduled for seven days, starting on May 13, 2024. D.I. 143, ¶21.

**IV. MOTION #1: SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NOS. 9,994,851 AND 10,227,590**

**A. Introduction**

In this litigation, the parties have asserted respective sets of patents against each other's products and their use. Based on the evidence developed to date, Sarepta agreed to no longer pursue non-infringement defenses for multiple NS Patents. In contrast, NS has manufactured a non-infringement defense by attempting to relitigate claim construction. Indeed, during *Markman*, the Court addressed the very aspect of the claims on which NS's non-infringement argument is based, precluding the argument NS now makes. Because NS's *only* non-infringement argument for the '851 and '590 Patents (collectively, the "Wilton Product Patents") contradicts the Court's *Markman* Order and is wrong as a matter of law, summary judgment of infringement is warranted.

During claim construction, the Court addressed a dispute over the phrase "in which uracil bases are thymine bases," which occurs in each asserted claim in the Wilton Product Patents. The Court concluded that the phrase applies to the *entire* claimed antisense oligonucleotide ("ASO"), including the claimed "base sequence" (selected from SEQ ID NO: 195). D.I. 248 ("*Markman* Op.") at 28-29 ("[T]he term '*in which uracil bases are thymine bases*' refers to the *entire antisense oligonucleotide*"); *id.* at 28 ("[T]he disputed term was *intended to modify the entire antisense oligonucleotide, not just the preceding base sequence limitation*."). Ignoring this construction, NS and its expert, Dr. Christine Esau, [REDACTED]

[REDACTED] This is nonsensical—the [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] And NS's other expert, Dr. Hastings, agrees with Sarepta's understanding [REDACTED]

[REDACTED] She further agrees [REDACTED]

[REDACTED]

As set forth in the concurrently filed Concise Statement of Facts, the undisputed facts show that under the Court's claim construction, NS's Viltepso<sup>®</sup> meets every limitation of the claims of the '851 and '590 Patents. NS cannot avoid summary judgment of infringement by manufacturing a claim reading that is inconsistent with this Court's claim construction and that even one of its own experts will not adopt.<sup>2</sup>

**B. NS Infringes the Asserted Claims of the Wilton Product Patents**

**1. Legal Standard on Infringement**

Summary judgment of infringement is properly granted when no reasonable jury could find that any limitation of the properly construed claim is missing from the accused product. *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001) ("An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents.").

"Where . . . the parties do not dispute any relevant facts regarding the accused product [and] disagree [only] over which of [the] possible meanings of [the particular claims at issue] is the proper one, the question of literal infringement collapses to one of claim construction and is

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<sup>2</sup> As described in the concurrently filed *Daubert* motion, Dr. Esau's non-infringement opinion should be excluded because it fails to apply the Court's *Markman* Order and is thus contrary to law. In addition, the claim construction she applies is inconsistent with the construction of the same term applied by NS's other expert on validity of the same patents.

thus amenable to summary judgment.” *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1320 (Fed. Cir. 2012) (quoting *Athletic Alts., Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996)); *In re Manchak Pat. Litig.*, 320 F. Supp. 2d 178, 186-87 (D. Del. 2002).

## 2. NS’s Only Non-Infringement Argument Is Based on a Claim Construction Contrary to the Court’s *Markman* Order

The claims of the Wilton Product Patents are directed to “[a]n antisense oligonucleotide . . . comprising a base sequence . . . wherein the base sequence comprises at least 12 consecutive bases of CUG AAG UUC UUG UAC UUC AUC C (SEQ ID No: 195), in which uracil bases are thymine bases . . .” During claim construction proceedings in this case, NS and its expert, Dr. Hastings, contended that the phrase “in which uracil bases are thymine bases” is indefinite because it could arguably be interpreted in two different ways: (1) as suggested by Sarepta and its expert, Dr. Stein, the phrase could be read to modify the ASO *as a whole*, or (2) according to NS and Dr. Hastings, the phrase could alternately be read to modify only the immediately preceding SEQ ID NO: 195 language. D.I. 166 at 47-48; D.I. 171, Exhibit 43 (Declaration of Michelle L. Hastings, Ph.D.), ¶¶117-144. The Court concluded in its *Markman* Opinion that the *entire* ASO is modified:

[W]hen read in light of the entirety of the Wilton Patents’ intrinsic record, a person of ordinary skill in the art would be clearly informed, with reasonable certainty, that ***the term “in which uracil bases are thymine bases,” refers to the entire antisense oligonucleotide.*** NS has not carried its burden of demonstrating, by clear and convincing evidence, that the term is indefinite. Accordingly, the Court, based on the intrinsic record, construes “in which uracil bases are thymine bases” to mean “the antisense oligonucleotide has thymine bases instead of uracil bases.”

*Markman* Op. at 28-29.

The Court further explained that “the disputed term was intended to modify ***the entire antisense oligonucleotide, not just the preceding base sequence limitation.***” *Id.* at 28. In other words, the phrase “in which uracil bases are thymine bases” modifies the entire ASO, including

[REDACTED]

the portion of the ASO corresponding to at least 12 consecutive bases of SEQ ID NO: 195. NS did not move for reconsideration of the *Markman* ruling.

NS and Dr. Esau acknowledge tha [REDACTED]

[REDACTED]

[REDACTED] Ex. 12, 7; Ex. 21, ¶¶39, 42. NS and Dr. Esau also acknowledge that

[REDACTED]

[REDACTED]

[REDACTED] Ex. 12, 6; Ex. 21, ¶¶28, 45; *see also* Ex. 21, ¶¶32-33; Ex. 31, 30:16-31:6, 31:12-16; SOF ¶¶1.24-1.25. But NS and Dr. Esau nevertheless now argue that [REDACTED]

[REDACTED]

[REDACTED] Ex. 12, 8; Ex. 21, ¶¶44-46; SOF ¶¶1.20-1.22. This is wrong for multiple reasons.

*First*, Dr. Esau’s non-infringement position violates the *Markman* ruling. The Court held that the phrase “in which uracil bases are thymine bases” applies to the entire ASO, including the preceding base sequence limitation (i.e., the portion of the ASO corresponding to at least 12 consecutive bases of SEQ ID NO: 195). *Markman* Op. at 28-29. Based on the court’s *Markman* ruling, the base sequence limitation also requires thymine bases, as it is part of the entire ASO. NS’s and Dr. Esau’s argument is therefore contrary to the Court’s *Markman* ruling, which already addressed the specific language of the claims on which NS’s non-infringement argument is based. *See Cryovac Inc. v. Pechiney Plastic Packaging, Inc.*, 430 F. Supp. 2d 346, 353-54 (D. Del. 2006) (granting summary judgment of infringement when the accused party’s non infringement defense was based on a claim construction not adopted by the court).

[REDACTED]

*Second*, Dr. Esau’s non-infringement position makes no sense. NS and Dr. Esau read the claims of the Wilton Product Patents as requiring [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 12, 5-10; Ex. 21, ¶¶24-46; Ex. 31, 33:2-10. [REDACTED]

[REDACTED] Ex. 31, 33:2-10; SOF ¶1.23. Such a nonsensical construction should be rejected. *See E.I. du Pont de Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1069 (Fed. Cir. 2019) (rejecting a “nonsensical” construction that “would require that the term . . . be considered alone, without reference to the surrounding claim language”); *see also Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1345 (Fed. Cir. 2009) (when claim language permits an operable construction, an inoperable construction is wrong).

*Third*, Dr. Esau’s non-infringement construction is irreconcilably inconsistent with the claim construction *of the same term* applied by NS’s other expert Dr. Hastings, who opines on the validity of the Wilton Product Patents. For example, when designing ASOs that purportedly fall within the claims of the Wilton Product Patents, [REDACTED]

[REDACTED] Ex. 22, ¶101; SOF ¶1.27. During her deposition, Dr. Hastings further acknowledged—contrary to Dr. Esau’s opinion—[REDACTED]

[REDACTED] Ex. 32, 157:11-158:15; SOF ¶1.26. Yet according to Dr. Esau, [REDACTED]

[REDACTED] Ex. 31, 31:24-33:1; SOF ¶1.28. Thus, Dr. Esau’s claim construction also violates the principle articulated by the Federal Circuit that “it is axiomatic

[REDACTED]

that claims are construed the same way for both validity and infringement.” *See, e.g., Source Search Techs. LLC v. Lending Tree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009) (collecting cases); *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017) (“Claim terms must be construed the same way for the purpose of determining invalidity and infringement.”).

### **3. There Is No Dispute that Viltepso® Meets All Limitations of the Claims of the Wilton Product Patents as Construed by the Court**

Applying the Court’s claim construction, the undisputed evidence shows that NS’s Viltepso® meets each and every limitation of the claims of the Wilton Product Patents. *See* Ex. 18, ¶¶234-265, 270-272, 274-283, 297 ([REDACTED]); Ex. 32, 157:11-158:15 ([REDACTED]); Ex. 31, 30:16-31:6, 31:12-16 ([REDACTED]), 39:14-40:17 ([REDACTED]); Ex. 12, 1-10; *see also* SOF ¶¶1.1-1.16, 1.19, 1.29-1.30. NS Japan and NS Pharma therefore directly infringe claims 1 and 2 of the ’851 Patent and claims 1 and 2 of the ’590 Patent at least by selling Viltepso® in the United States, and summary judgment is warranted. SOF ¶¶1.17-1.18; *see Cryovac*, 430 F. Supp. 2d at 353-54 (summary judgment of infringement should be entered when there is no genuine issue of material fact regarding infringement).

### **C. Conclusion**

Accordingly, Sarepta is entitled to summary judgment of infringement of claims 1 and 2 of the ’851 Patent and claims 1 and 2 of the ’590 Patent.

**V. MOTION #2: SUMMARY JUDGMENT OF NO LOST PROFITS**

**A. Introduction**

NS Japan seeks over [REDACTED] in lost profits based on sales by its subsidiary NS Pharma<sup>3</sup>, *which is not a plaintiff in NS Japan’s infringement case*. The Federal Circuit has *never affirmed* such an award. But even if this approach were viable, NS Japan would need to prove that NS Pharma’s profits flow “inexorably” to NS Japan. NS Japan fails to do so both as a matter of law and by a failure of proof. Summary judgment of no lost profits is proper.

**B. Legal Standard**

The availability of lost profits is a question of law. *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995). NS Japan bears the burden to prove damages. *Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 660 (Fed. Cir. 2017) (noting that damages cannot be left to conjecture or guesswork). It is axiomatic that “a patentee may not claim, as its own damages, the lost profits of a related company.” *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1375 (Fed. Cir. 2015), *vacated sub nom. on other grounds Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, 577 U.S. 1099 (2016). The Federal Circuit has warned that related companies “may not enjoy the advantages of their separate corporate structure and, at the same time, avoid the consequential limitations of that structure.” *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). “Normally, if the patentee is not selling a product, by definition there can be no lost profits.” *Rite-Hite*, 56 F.3d at 1548.

The Federal Circuit has never affirmed an award of lost profits based on the profits of a non-party flowing inexorably to its related patent-holding entity who itself does not sell a product in the U.S. *See, e.g., Fujitsu Ltd. v. Tellabs, Inc.*, 539 F. App’x 1005, 1007 (Fed. Cir. 2013)

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<sup>3</sup> “NS Japan” refers to Nippon Shinyaku Co. Ltd., a Japanese company. *See* D.I. 324 at ¶¶5-7. “NS Pharma” refers to NS Pharma Inc., a NS Japan subsidiary incorporated in Delaware. *Id.*



[REDACTED]

(declining appeal regarding inexorable flow lost profits on procedural grounds). In *Mars, Inc. v. Coin Acceptors, Inc.*, the Federal Circuit declined to decide whether the “inexorable flow” theory could support a recovery of lost profits. 527 F.3d 1359, 1367 (Fed. Cir. 2008) (“[W]e, like the *Poly-America* court, need not decide whether a parent company can recover on a lost profits theory when profits of a subsidiary actually *do* flow inexorably up to the parent.” (emphasis in original)). *Mars* cautioned that although a related company’s lost sales “may have caused harm” to its parent, that alone is insufficient to establish entitlement to an award of lost profits. *Id.* at 1365.

Subsequently, some courts have held that the inexorable flow theory is legally wrong. *See, e.g., Mars, Inc. v. TruRx LLC*, Case No. 6:13-cv-526, 2016 WL 4061981, at \*2 (E.D. Tex. Apr. 29, 2016) (“To date, no case decided by the Federal Circuit has allowed a patentee to recover the lost profits of a related company as its own under the inexorable flow theory.”); *Copperhead Indus., Inc. v. Changer & Dresser, Inc.*, Case No. 1:18-cv-01228, 2020 WL 429485, at \*2 (N.D. Ala. Jan. 28, 2020).

Even lower courts that have not outright rejected “inexorable flow” as legal error routinely grant summary judgment of no lost profits. *See, e.g., Intuitive Surgical, Inc. v. Auris Health, Inc.*, Case No. 18-1359-MN, 2021 WL 3662842, at \*2-4 (D. Del. Aug. 18, 2021); *Fujitsu Ltd. v. Tellabs, Inc.*, Case No. 09 C 4530, 2013 WL 2285794, at \*6-8 (N.D. Ill. May 23, 2013); *Edgewell Personal Care Brands, LLC v. Munchkin, Inc.*, Case No. CV 18-3005 PSG, 2022 WL 18932811, at \*17 (C.D. Cal. July 6, 2022); *Kowalski v. Mommy Gina Tuna Res.*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008).

### **C. Summary Judgment of No Lost Profits Is Proper**

#### **1. NS Japan’s Lost Profits Theory Fails as a Matter of Law**

Consistent with the weight of authority, summary judgment of no lost profits should be granted here. Even if the legal theory of “inexorable flow” were sound, NS Japan cannot prove

[REDACTED]

inexorable flow by [REDACTED] as a matter of law. There is no genuine issue of material fact for trial.

*Fujitsu* is on point. After thoroughly surveying the case law, the court granted summary judgment of no lost profits where a patentee argued its subsidiary's profits "inexorably flowed" to it under a transfer pricing arrangement. 2013 WL 2285794, at \*3-8. There, like here, the patentee-parent Japanese company sold products to its non-party U.S. subsidiary, which in turn sold to U.S. customers, and sought lost profits based on the amount it charged its U.S. subsidiary. *Id.* at \*6-7. Rejecting this claim, the court reasoned it was "clear that none of the payments by [the subsidiary] to [the patentee] are the transfer of profits or the inexorable flow of profits." *Id.* at \*7-8. The court observed that the transfer price paid by the subsidiary was "more of an ***agreed upon inter-company penalty rather than the flow of profit***" and was "***regulated and calculated*** according to U.S. Tax Code requirements ***so as to avoid the consequences*** of 26 U.S.C. § 482." *Id.* at \*8. *Fujitsu* points out that this provision relates to the IRS's ability to allocate ***income*** and ***deductions*** among transfer pricing tax payers, ***not profits***. *See id.* The *Fujitsu* court concluded that the "fact that [the patentee] periodically alters the price it charges [the subsidiary], which, of course, is tax deductible to [the subsidiary] as a cost paid by [the subsidiary], ***does not convert*** [the patentee's] ***tax avoidance strategy to the inexorable flow of profits*** required by *Mars*, 527 F.3d at 1367." *Id.* Thus, the court granted summary judgment of no lost profits. *Id.* at \*9.

The rationale behind *Fujitsu*'s holding is likewise fatal to NS Japan's lost profits claim for two key reasons. ***First***, [REDACTED]  
[REDACTED]. *See Fujitsu*, 2013 WL 2285794, at \*8; *see also* 26 U.S.C. § 482. This is not, as a matter of law, the "inexorable flow" of profits. *Fujitsu*, 2013 WL 2285794, at \*8. Just as in *Fujitsu*, there is no dispute that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]—to prove inexorable flow. *See* Ex. 49, pgs. 60, 79-81; Ex. 53, NS00036897-98; Ex. 50, 112:15-113:3; SOF ¶¶2.13-15. NS Japan [REDACTED]. The “[REDACTED]” term provides [REDACTED]

[REDACTED] Ex. 49, pgs. 24-25; Ex. 53, NS00036898; SOF ¶¶2.6-2.7, 2.13-2.15. And the “[REDACTED]

[REDACTED]

[REDACTED] Ex. 49, pg. 24; Ex. 53, NS00036897-98; SOF ¶¶2.8-2.10, 2.13-2.15. As defined in the Agreement, however, [REDACTED]

[REDACTED] *Id.*

Thus, no “inexorable” profit flows to NS Japan.

NS Japan’s own outline of the Agreement acknowledges [REDACTED]

Exs. 51 & 52, NS00065827 (“[REDACTED]

[REDACTED]

[REDACTED]”); SOF ¶2.14.

Thus, just as in *Fujitsu*, [REDACTED]

[REDACTED]

[REDACTED].” 2013 WL 2285794, at \*8.

*Second*, [REDACTED]

[REDACTED] SOF ¶¶2.3-2.5. [REDACTED]

[REDACTED]

[REDACTED] *See Fujitsu*, 2013 WL 2285794 at \*6-7; *see also* Ex. 53, NS00036894; Ex. 49, pg. 60. There is no dispute that NS Japan and NS Pharma are distinct corporate entities. *See, e.g.*, Ex. 49, pgs. 7-8; *see also* D.I. 324 at ¶¶5-7; SOF ¶¶2.1-2.2. [REDACTED]

[REDACTED]

[REDACTED] Ex. 50, 112:11-14; Ex. 49, pg. 60; *see also* Ex. 53, NS00036894; Ex. 40, 59:18-60:6; SOF ¶¶2.3-2.5. NS Japan’s expert, Mr. Hosfield,

[REDACTED]

Ex. 50, 114:9-19 ([REDACTED]); SOF ¶¶2.11. NS Pharma cannot have its cake and eat it too—[REDACTED]

[REDACTED] *See Intuitive Surgical*, 2021 WL 3662842, at \*3 (“[T]he Federal Circuit has explained that two companies that benefit from dividing patent ownership from sale of the patented product must also accept the consequence that the patent owner will be unable to claim the lost profits experienced by the seller.”).

## 2. NS Japan Cannot as a Matter of Law Prove Inexorable Flow of Profits

NS Japan’s lost profits claim independently fails for a lack of proof. NS Japan must not “le[ave] [damages] to conjecture by the jury. They must be proved, and not guessed at.” *Promega Corp.*, 875 F.3d at 660 (internal quotations omitted). NS Japan advances a lost profits claim that

[REDACTED]

[REDACTED]

[REDACTED]. Ex. 53, NS00036897-98; SOF ¶¶2.13-2.17.

Judge Noreika recently granted summary judgment of no inexorable flow lost profits where

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<sup>4</sup> Mr. Hosfield relies on *Polaris Indus., Inc. v. Arctic Cat, Inc.*, No. 15-cv-4129, 2019 WL 1118518, \*8 (D. Minn. Mar. 11, 2019) (Ex. 49, pg. 60, n.355), which supports *Sarepta’s* position. The court emphasized that “[s]howing inexorable flow of profits from one entity to another is an *extremely high bar to meet*.” *Id.* at \*8. And the patentee only survived summary judgment because: (1) both companies shared a bank account where the proceeds from sales of the specific product were deposited; (2) the patentee controlled sales revenues at all times; and (3) the patentee bore all costs related to the sales. *Id.* None of these factors are present here.

[REDACTED]

a patentee offered only “conclusory statements” to support its claim. *See Intuitive Surgical*, 2021 WL 3662842, at \*3. Likewise, here, [REDACTED]

[REDACTED] Ex. 49, pg. 60; Ex. 50, 112:15-22; *see* SOF ¶¶2.13, 2.16-2.17. This (lack of) analysis fails. But NS’s failure is even clearer than that in *Intuitive*. There is no dispute that [REDACTED]

[REDACTED]. Ex. 49, pg. 81; Ex. 39, 110:3-8; SOF ¶2.12. The only evidence of [REDACTED]

[REDACTED]. Ex. 49, pg. 25; Exs. 56, 54; SOF ¶2.12. [REDACTED]

[REDACTED] Ex. 49, pgs. 25-26; Ex. 57; SOF ¶2.12. Although NS Japan asserts that its lost profits exceed [REDACTED]

[REDACTED]

[REDACTED] (to the extent they exist). *See* Ex. 49, pgs. 60, 80-81; Ex. 50, 120:24-121:11; SOF ¶¶2.13, 2.16-2.17. Moreover, Mr. Hosfield [REDACTED]

[REDACTED] Ex. 50, 120:24-121:11; SOF ¶¶2.16-2.17.

Without proof of [REDACTED], these “profits” are not inexorable.<sup>5</sup> NS Japan cannot “le[ave] [damages] to conjecture by the jury.” *Promega Corp.*, 875 F.3d at 660. Such “conclusory statements . . . are insufficient to support a collective assertion of lost profits[,]” and summary judgment is appropriate. *Intuitive Surgical*, 2021 WL 3662842, at \*3.

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<sup>5</sup> As the IRS explains: “U.S. corporations operating through related enterprises, including affiliated foreign corporations, have long attempted to manipulate their internal allocations and transactions in order to avoid U.S. income. . . . To combat such abuse, and to ensure that transactions between related parties reflect economic reality, Congress — for almost 100 years — has given the IRS the ‘broad authority’ to evaluate the pricing of transactions between commonly controlled parties, and to allocate certain tax items (including gross income) ‘if [it] determines that such . . . allocation is necessary in order to prevent evasion of taxes or clearly to reflect the income of any such’ entities. I.R.C. § 482.” Brief for the Appellant at 4-5, *Medtronic, Inc. & Consol. Subsidiaries v. Comm’r of Internal Revenue*, 900 F.3d 610, 612 (8th Cir. 2018) (No. 17-1866) (Ex. 63).

[REDACTED]

**D. Conclusion**

Summary judgment of no lost profits should be granted.

**VI. MOTION #3: SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND NO WALKER PROCESS FRAUD**

**A. Introduction**

Summary judgment of no inequitable conduct is warranted both because NS applied the *wrong legal standard* in evaluating intent to deceive the PTO and because NS failed to identify *any* evidence of an intent to deceive. Because the intent showing for inequitable conduct and *Walker Process* claims are “nearly identical” (*see infra* § VI.D.4), summary judgment of no *Walker Process* fraud is also warranted.

NS relies on a “patent law expert,” Dr. Scott Kamholz, to argue specific intent. [REDACTED]

[REDACTED]

[REDACTED] But Dr. Kamholz applied the wrong legal standard. After reviewing the applicable evidence, he opined only that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

This is fatal to NS’s inequitable conduct defense and counterclaim. “To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the *specific intent* to deceive the PTO. A finding that the misrepresentation or omission amounts to gross

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<sup>6</sup> Dr. Kamholz’s expert testimony as to anyone’s intent or state of mind is legally improper and the subject of Sarepta’s contemporaneously filed *Daubert* motion. This motion is not dependent on exclusion of his testimony. [REDACTED]

[REDACTED]

[REDACTED]

negligence or negligence under a ‘*should have known*’ standard does not satisfy this intent requirement.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (en banc). Because Dr. Kamholz’s argument is based on an incorrect and lower legal standard, and because he admittedly could not meet the correct higher standard, his inequitable conduct theories fail as a matter of law and summary judgment is appropriate.

NS has also failed to identify *any* evidence of intent to deceive the PTO by the inventors or anyone involved with the prosecution of the Wilton Patents. Based on this record, no trier of fact could reasonably conclude that the single most reasonable inference is that anyone involved with the prosecution of the Wilton Patents possessed the specific intent to deceive the PTO. Because NS cannot satisfy the intent prong of its inequitable conduct and *Walker Process* fraud allegations, the Court should grant summary judgment for Sarepta and UWA with respect to both.<sup>7</sup>

## **B. Factual Background**

### **1. The Prosecution of the Wilton Patents**

The Wilton Patents claim priority to a PCT application filed on June 28, 2005. Ex. 11, item (22); SOF ¶3.1. On March 26, 2013, Dr. Wilton and Dr. Fletcher signed an inventorship declaration that was subsequently submitted to the PTO during prosecution of the Wilton Patents. Ex. 14, SRPT-VYDS-002988-90; SOF ¶¶3.2-3.5.

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<sup>7</sup> To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. *Therasense*, 649 F.3d at 1287. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. *Id.* Sarepta’s motion relies on the failure of proof with respect to the intent prong of the inequitable conduct defense. Sarepta disputes that the purportedly withheld information is material, but resolution of the materiality issue is unnecessary for Sarepta to prevail on this motion.

[REDACTED]

On September 22, 2017, Ms. Mandragouras submitted the Harding paper<sup>8</sup> to the PTO in an Information Disclosure Statement (IDS) in the application that later issued as the '851 patent. Ex. 14, SRPT-VYDS-0003156-63 (Form PTO/SB/08a) at -57; SOF ¶¶3.6, 3.8. The Examiner considered the Harding paper, as reflected by the Examiner's initials at the bottom of each page of the IDS along with her annotation "ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH." Ex. 14, SRPT-VYDS-0004648-55 (Form PTO/SB/08a Considered) at -49; SOF ¶3.7.<sup>9</sup> The Harding paper was also submitted to the PTO, and considered by the Examiner, during prosecution of the applications that issued as the '590 and '827 patents. Ex. 15, SRPT-VYDS-0005451-561 (Form PTO/SB/08a) at -479, SRPT-VYDS-0005626-737 (Form PTO/SB/08a Considered) at -729; Ex. 16, SRPT-VYDS-0006287-398 (Form PTO/SB/08a) at -315, SRPT-VYDS-0006478-589 (Form PTO/SB/08a Considered) at -506; SOF ¶¶3.11-3.16.

## 2. NS's Inequitable Conduct Arguments

### a. The Inventorship Declaration

NS, through the reports of Dr. Kamholz, asserts [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 24, ¶31; Ex. 26, ¶2. Dr. Kamholz [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 24, ¶¶32, 38, 51-53. Dr. Kamholz [REDACTED]

<sup>8</sup> Harding et al., "The Influence of Antisense Oligonucleotide Length on Dystrophin Exon Skipping," *Molecular Therapy*, Vol. 15, No. 1, 157-166 (2007). Ex. 55.

<sup>9</sup> On March 28, 2018, a different law firm took over prosecution and Ms. Mandragouras's involvement in the application ceased. Ex. 14, SRPT-VYDS-0004929-34; SOF ¶3.9. That firm also prosecuted the applications that issued as the '590 and '827 patents. Ex. 15, SRPT-VYDS-0005352-53, -603-609; Ex. 16, SRPT-VYDS-0006187-88, -244-50; SOF ¶3.10.



[REDACTED]

[REDACTED]

[REDACTED] *Id.* ¶¶32, 33, 55; Ex. 26, ¶27.

**b. Table 39 of the Specification**

Dr. Kamholz also opines [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Ex. 24, ¶¶34-35, 57-72. Dr. Kamholz asserts that the inventors and Ms. Mandragouras “knew or should have known” [REDACTED]

[REDACTED] *Id.* ¶¶36-37, 73-75, 77-79.

**c. Dr. Kamholz’s Opinions Regarding Knowledge**

[REDACTED]

[REDACTED]

[REDACTED] Ex. 33, 48:3-13, 49:8-13, 50:21-24.

[REDACTED]

[REDACTED] *Id.* 79:10-13, 79:18-21, 80:1-4.

**C. Legal Standards on the Intent Requirement of the Inequitable Conduct Defense**

“To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the *specific intent* to deceive the PTO. A finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘*should have known*’ standard does not satisfy this intent requirement.” *Therasense*, 649 F.3d at 1290 (citing *Star Sci. Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) and *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988)). In cases involving nondisclosure of

information, “the accused infringer must prove *by clear and convincing evidence* that the applicant *knew* of the reference, *knew* it was material, and *made a deliberate decision* to withhold it.” *Id.* To prevail on its inequitable conduct claim, NS must prove intent (and materiality) by clear and convincing evidence. *Id.* “[T]o meet the clear and convincing evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’ Indeed, the evidence ‘must be sufficient to *require* a finding of deceitful intent in light of all the circumstances.’” *Id.* (quoting *Star*, 537 F.3d at 1366 and *Kingsdown*, 863 F.2d at 873) (emphasis in original). After *Therasense*, “[a] court can no longer infer intent to deceive from non-disclosure of a reference solely because that reference was known and material.” *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1372-73 (Fed. Cir. 2012).

Summary judgment is appropriate when, as here, a party has failed to introduce evidence sufficient to establish the existence of an essential element of that party’s case in accordance with the applicable standard of proof. *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1319-22 (Fed. Cir. 2010) (granting summary judgment of no inequitable conduct where defendant “had offered no evidence that could succeed in proving deceptive intent by clear and convincing evidence”).

#### **D. Argument**

##### **1. Summary Judgment of No Inequitable Conduct by Dr. Wilton, Dr. Fletcher, Ms. Mandragouras, and Any Other Person Involved with Prosecution of the Wilton Patents Is Warranted**

Under *Therasense*, NS can only prevail on its defense and counterclaim of inequitable conduct if it can prove—by clear and convincing evidence—that the inventors or Ms. Mandragouras 1) *knew* they were making a misrepresentation to the PTO at the time they made it or 2) *knew* of the information NS contends was withheld, *knew* it was material, and *made a deliberate decision* to withhold it. *Therasense*, 649 F.3d at 1290. NS engaged Dr. Kamholz to provide expert analysis and opinions to support their inequitable conduct allegations. *See, e.g.*,

Ex. 24, ¶1. In his expert reports, Dr. Kamholz advances an incorrect legal standard—repeatedly opining as to what Dr. Wilton, Dr. Fletcher, or Ms. Mandragouras “knew or should have known.”

*Id.* ¶¶32-33, 36-37, 55, 73, 78-79; Ex. 26, ¶¶2, 12, 17, 21, 27, 29-30; SOF ¶3.17. In his deposition,

Ex. 33, 48:3-13, 49:8-13, 50:21-24, 79:10-13, 79:18-21, 80:1-4; SOF ¶3.19.

Ex. 33, 48:11-49:7; SOF ¶¶3.18-3.21.

NS’s and Dr. Kamholz’s admitted inability to present evidence of actual knowledge is fatal to its case. The “knew or should have known” standard was expressly rejected by the en banc Federal Circuit. *Therasense*, 649 F.3d at 1290. In doing so, the Federal Circuit reviewed the Supreme Court precedent that originated the inequitable conduct doctrine and explained that “[i]n each of those cases, the patentee acted knowingly and deliberately with the purpose of defrauding the PTO and the courts.” *Id.* (citing cases). It explained that these cases supported using the “requirement of knowledge and deliberate action” for the intent standard. *Id.* As such, the Federal Circuit held that “[a] finding that the misrepresentation or omission amounts to gross negligence or negligence under a ‘*should have known*’ standard does not satisfy this intent requirement.” *Id.*

Because NS’s argument is based on an incorrect and lower legal standard, and because NS admittedly cannot meet the correct higher standard, its inequitable conduct theories fail as a matter of law and summary judgment is appropriate. *Joy MM Del. Inc. v. Cincinnati Mine Mach. Co.*, 834 F. Supp. 2d 360, 385 (W.D. Pa. 2011), *rev’d in part on other grounds*, 497 F. App’x 970 (Fed. Cir. 2012) (expert opinions applying the “wrong legal standards” for inequitable conduct “are simply insufficient to avoid summary judgment”); *see also Straumann Co. v. Lifecore*

[REDACTED]

*Biomedical Inc.*, 278 F. Supp. 2d 130, 135 (D. Mass. 2003) (expert opinion “based on an erroneous legal standard . . . cannot defeat summary judgment”).

## 2. Under the Correct Legal Standard, NS Has Failed to Proffer Sufficient Evidence to Survive Summary Judgment

To survive a Rule 12 motion, NS’s counterclaim of inequitable conduct only needed to satisfy the “plausibility” standard of pleading set forth in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). At the summary judgment stage, however, NS’s burden is much greater: it must show that “a factfinder could reasonably conclude that ***deceptive intent is the single most reasonable inference.***” *Sysmex Corp. v. Beckman Coulter, Inc.*, Case No. 19-1642, 2022 WL 1503987, at \*4 (D. Del. May 6, 2022), *report and recommendation adopted*, 2022 WL 1744573 (D. Del. May 31, 2022). Further, NS must identify evidence sufficient to establish the essential elements of its defense, that either 1) Dr. Wilton, Dr. Fletcher, or Ms. Mandragouras ***knew*** they were making an alleged misrepresentation to the PTO at the time they made it or 2) they ***knew*** of information NS contends was withheld, ***knew*** it was material, and ***made a deliberate decision*** to withhold it. *See Therasense*, 649 F.3d at 1290.

After months of fact and expert discovery, NS has failed to identify sufficient evidence upon which a factfinder could reasonably conclude that anyone associated with the filing and prosecution of the Wilton Patents had ***any*** intent to deceive the PTO. As discussed above, NS engaged Dr. Kamholz (even though legally improper) to analyze and opine on inequitable conduct. Yet, the most Dr. Kamholz could opine was that these individuals “knew or should have known” information was allegedly false or misleading. Ex. 24, ¶¶32-33, 36-37, 55, 73, 78-79; Ex. 26, ¶¶2, 12, 17, 21, 27, 29-30. Even then, Dr. Kamholz [REDACTED]

[REDACTED] (Ex. 33, 48:11-49:7) [REDACTED]

[REDACTED] (*id.*)

[REDACTED]

48:3-13, 49:8-13, 50:21-24, 79:10-13, 79:18-21, 80:1-4). Because NS has failed to identify any evidence of intent, it has also necessarily failed to show that specific intent to deceive is the single most reasonable inference that can be drawn from the evidence, as required by *Therasense*. *Therasense*, 649 F.3d at 1290-91.

**a. NS Failed to Identify Any Evidence of Intent to Deceive with Respect to the Inventorship Declaration**

NS identifies no evidence that the inventors or Ms. Mandragouras *knew* that the inventorship declaration was “false or misleading.” [REDACTED]

[REDACTED] Ex. 33, 48:3-13, 49:8-13, 50:21-24.

The Harding 2007 paper [REDACTED]

[REDACTED] was in fact *submitted* to the Examiner during prosecution—even though it was not prior art—and the Examiner confirmed that she considered that paper in the course of her examination. Ex. 14, SRPT-VYDS-0003156-63 (Form PTO/SB/08a) at -57, SRPT-VYDS-0004648-55 (Form PTO/SB/08a Considered) at -49; Ex. 15, SRPT-VYDS-0005451-561 (Form PTO/SB/08a) at -479, SRPT-VYDS-0005626-737 (Form PTO/SB/08a Considered) at -729; Ex. 16, SRPT-VYDS-0006287-398 (Form PTO/SB/08a) at -315, SRPT-VYDS-0006478-589 (Form PTO/SB/08a Considered) at -506; SOF ¶¶3.6-3.7, 3.13-3.16. The Examiner’s express and repeated consideration of Harding distinguishes this case from *EIS Inc. v. IntiHealth Ger GmbH*, where that Examiner specifically requested that the applicants highlight significant documents, noting that “forcing the Examiner to find ‘a needle in a haystack’ is ‘probative of bad faith.’” *See EIS Inc. v. IntiHealth Ger GmbH*, C.A. No. 19-1227-GBW, 2023 WL 6799332, at \*9 (D. Del. Aug. 23, 2023).

NS’s allegations regarding the inventorship declaration are similar to allegations the Federal Circuit held were insufficient for intent even under the more-lenient pre-*Therasense* standard. *See Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1332 (Fed. Cir. 2009). In

[REDACTED]

*Vita-Mix*, the party asserting inequitable conduct asserted that an inventor submitted a declaration containing an allegedly false statement and identified a reference allegedly showing that the statement was false. *Id.* The inventor explained at his deposition that “regardless of whether the statement is actually false, he believed the statement to be true at the time he made it.” *Id.* In affirming summary judgment of no inequitable conduct, the Federal Circuit held that “[w]ith no other evidence in the record, the district court correctly found that [the party alleging inequitable conduct] made no genuine showing of deceptive intent.” *Id.*

Similar to *Vita-Mix*, NS bases its inequitable conduct claim, in part, on an inventorship declaration allegedly containing false information. Even if it contained false information that was material to patentability—and it does not—NS has provided no evidence that Dr. Wilton or Dr. Fletcher *knew* the inventorship declaration to be false at the time they signed it. *See* Ex. 36, 198:23-200:9. This failure dooms NS’s inequitable conduct claim under even the lower, pre-*Therasense* standard.

**b. NS Failed to Identify Any Evidence of Intent to Deceive with Respect to the Data in Table 39**

[REDACTED]

[REDACTED]

[REDACTED] Ex. 38, 152:20-153:6; SOF ¶3.22. [REDACTED]

[REDACTED]

[REDACTED] Ex. 36, 200:1-3, 5-9; SOF ¶¶3.23-3.24. And Ms. Mandragouras was not aware of any alleged error in Table 39. *See* Ex. 37, 67:20-23. Accordingly, NS cannot establish any evidence of *knowledge* of an error during prosecution of the patents-in-suit, let alone

intent to deceive the PTO. NS's arguments with respect to Table 39 thus fail for the same reasons as its arguments based on the inventorship declaration.<sup>10</sup>

### 3. No Disputed Factual Issues Exist

Although NS may contend that intent is a question of fact that requires a trial to resolve, at summary judgment, a court assesses whether the party advancing the defense of inequitable conduct has provided sufficient evidence “such that, at the trial stage, a factfinder could reasonably conclude that deceptive intent is *the single most reasonable inference*.” *Sysmex*, 2022 WL 1503987, at \*4. NS produced no such evidence and, accordingly, no such reasonable conclusion can be made.

When, as here, a party has failed to provide sufficient evidence to support a finding of intent by clear and convincing evidence, courts have frequently granted summary judgment of no inequitable conduct. For example, in *Greatbatch Ltd. v. AVX Corp.*, the court found that the defendant had cited “no evidence of intent to deceive aside from [the inventor’s] failure to disclose” a prior art reference. C.A. No. 13-723-LPS, 2015 WL 9171042, at \*12-13 (D. Del. Dec. 11, 2015). In granting summary judgment, the court held that “[b]ecause [the inventor’s] failure to disclose the [omitted] prior art, by itself, is insufficient to show intent—yet that is the only evidence of intent to which [the party alleging inequitable conduct] points—the record does not support a reasonable finding that [the inventor] acted with deceptive intent.” *Id.* at \*13 (citing *Therasense*, 649 F.3d at 1290); accord *Baxter Int’l, Inc. v. CareFusion Corp.*, Case No. 15 C 9986,

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<sup>10</sup> A purportedly improper priority claim to the 2005 PCT application was the focus of NS’s Counterclaim. See, e.g., D.I. 344 at Countercl. ¶¶73-76. Despite proffering extensive “state of mind testimony,” neither Dr. Kamholz nor any other NS expert offers opinions or evidence as to the intent of anyone involved with the prosecution as to that priority claim. Indeed, Dr. Kamholz’s expert reports do not provide any evidence or opinions regarding whether the Wilton Patents improperly asserted priority to the 2005 PCT Application. See generally Exs. 24, 26. Because NS has failed to offer any such evidence, summary judgment with respect to the priority claim is appropriate. See Ex. 36, 198:23-200:9.

2022 WL 981115, at \*8 (N.D. Ill. Mar. 31, 2022) (rejecting argument that summary judgment motions for no inequitable conduct are rarely granted, noting that “[e]ven if that may have been true pre-*Therasense*, it is no longer the case” and collecting cases); *see also Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1351 (Fed. Cir. 2017) (affirming summary judgment of no inequitable conduct because the “evidence was insufficient to permit a finding of the intent required”); *Skillz Platform Inc. v. Aviagames Inc.*, Case No. 21-cv-02436-BLF, 2023 WL 6542147, at \*7-8 (N.D. Cal. Oct. 6, 2023) (granting summary judgment of no inequitable conduct when the only intent theory was based on “speculation”); *Bausch Health Ir. Ltd. v. Padagis Isr. Pharms. Ltd.*, 603 F. Supp. 3d 107, 124, 116-17 (D.N.J. 2022) (similar); *Trading Techs. Int’l, Inc. v. IBG LLC*, Case No. 10 C 715, 2020 WL 7013964, at \*4-5 (N.D. Ill. Nov. 29, 2020) (similar). This is another such case.

**4. NS’s *Walker Process* Antitrust Claim Fails Because There Is No Evidence that the Wilton Inventors and Prosecution Attorneys Specifically Intended to Deceive the PTO**

NS’s *Walker Process* antitrust claim fails because, as with its inequitable conduct claim, there is no evidence of specific intent to deceive the PTO.

The party asserting a *Walker Process* claim must establish that the patents at issue were fraudulently obtained. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177-78 (1965). The fraud must be based on “independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.*, that the patent would not have issued but for the misrepresentation or omission.” *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998). This requires a showing “nearly identical” to that required to prove inequitable conduct. *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, C.A. No. 17-275-LPS, 2019 WL 668843, at \*3 (D. Del. Feb. 19, 2019); *see also Inline Packaging, LLC v. Graphic Packaging Int’l, LLC*, 962 F.3d 1015, 1025 (8th Cir. 2020) (the evidentiary showing



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necessary to establish knowing and willful fraud “seems to be ‘nearly identical’ to the evidentiary showing of inequitable conduct”). A determination that a plaintiff has failed to establish a genuine dispute of material fact on an inequitable conduct claim is therefore grounds to grant summary judgment on the *Walker Process* claim. *See, e.g., Pac. Biosciences*, 2019 WL 668843, at \*3.

NS has failed to present any evidence that anyone involved with the prosecution of the Wilton Patents possessed the specific intent to deceive the PTO and there is therefore no genuine issue of material fact for trial. *See supra* §§ VI.D.1-3. Summary judgment in Sarepta’s favor on NS’s *Walker Process* counterclaim is also warranted on this basis.

#### **E. Conclusion**

NS has failed to proffer evidence sufficient to meet its burden of satisfying the intent requirement of its inequitable conduct and *Walker Process* fraud allegations. Summary judgment as to both is warranted.

### **VII. CONCLUSION**

For the forgoing reasons, Sarepta and UWA respectfully request that the Court grant summary judgment based on the three separate grounds briefed herein, to be evaluated in the order presented herein, and specified in the accompanying motions.



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December 11, 2023

**CERTIFICATE OF SERVICE**

I hereby certify that on December 11, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 11, 2023, upon the following in the manner indicated:

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